WHAT IS CLAIMED IS:

- 1. A protein composition, free from total cell components, the protein being characterized as having a molecular weight of about 13 kD, as determined by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS/PAGE), and being isolatable from B. burgdorferi.
- 2. The protein composition of claim 1, wherein the composition further comprises *B. burgdorferi* outer membrane proteins OspA, OspB, OspC or OspD, in combination with a pharmacologically acceptable diluent or carrier.
- 3. A purified protein having the following characteristics:
 - (a) being iso atable from B. burgdorferi;
 - (b) being present on the surface of B. burgdorferi cells that lack the outer membrane proteins OspA, OspB, OspC and OspD;
 - (c) being sensitive to cleavage with proteinase K;
 - (d) having a molecular weight of about 13 kD, as determined by SDS/PAGE;
 - (e) having binding affinity for the monoclonal antibodies termed 15G6 and 7D4.
- 4. The purified protein of claim 3, further defined as being isolated from B. burgdorferi cells.



The purified protein of claim 3, further defined as being a recombinant protein obtained from a recombinant host cell that includes a nucleic acid segment that expresses said protein.

- 6. The purified protein of claim 3, in combination with a pharmacologically acceptable diluent or carrier.
- 7. The purified protein of claim 3, linked to a detectable label, the label being a radioactive label, a flourogenic label, a nuclear magnetic spin resonance label, biotin or an enzyme that generates a colored product upon contact with a chromogenic substrate.
- 8. An antibody that has binding affinity for the protein of claim 3.
- 9. The antibody of claim 8, linked to a detectable label, the label being a radioactive label, a flourogenic label, a nuclear magnetic spin resonance label, biotin or an enzyme that generates a colored product upon contact with a chromogenic substrate.
- 10. The antibody of claim 9, linked to an alkaline phosphatase, hydrogen peroxidase or glucose oxidase enzyme.
- 11. The antibody of claim 8, further defined as a monoclonal antibody.

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- 12. The antibody of claim 11, further defined as the monoclonal antibody 15G6 or 7D4.
- 13. A method for detecting B. burgdorferi in a sample, comprising contacting a sample suspected of containing B. burgdorferi with a first antibody in accordance with claim 8, under conditions effective to allow the formation of immune complexes, and detecting the immune complexes so formed.
- 14. The method of claim 13, wherein the first antibody is the monoclonal antibody 15G6 or 7D4.
- 15. The method of claim 13, wherein the first antibody is linked to a detectable label and the immune complexes are detected by detecting the presence of the label.
- 16. The method of claim 13, wherein the immune complexes are detected by means of a second antibody linked to a detectable label, the second antibody having binding affinity for said first antibody.
- 17. The method of claim 13, further defined as a method of diagnosing Lyme Disease, wherein the sample suspected of containing B. burgdorferi is a clinical sample obtained from a patient suspected of having Lyme Disease and the detection of immune complexes is indicative of a patient with Lyme Disease.
- 18. A method for detecting antibodies to B. burgdorferi, comprising contacting a sample suspected of containing antibodies to B. burgdorferi with a protein in accordance with claim 3,



under conditions effective to allow the formation of immune complexes, and detecting the immune complexes so formed.

- 19. The method of claim 18, wherein said protein is linked to a detectable label and the immune complexes are detected by detecting the presence of the label.
- 20. The method of claim 18, wherein the immune complexes are detected by means of a second antibody linked to a detectable label, the second antibody having binding affinity for said protein.
- 21. The method of claim 18, wherein the immune complexes are detected by means of a second antibody linked to a detectable label, the second antibody having binding affinity for the first, anti-B. burgdorferi antibodies.
- 22. The method of claim 18, further defined as a method of diagnosing Lyme Disease, wherein the sample suspected of containing antibodies to B. burgdorferi is a clinical sample obtained from a patient suspected of having Lyme Disease and the detection of immune complexes is indicative of a patient with Lyme Disease.
- 23. An immunodetection kit comprising, in suitable container means, a protein in accordance with claim 3 or a first antibody in accordance with claim 8, and an immunodetection reagent.



- 24. The immunodetection kit of claim 23, wherein the immunodetection reagent is a detectable label that is linked to said protein or said first antibody.
- 25. The immunodetection kit of claim 23, wherein the immunodetection reagent is a detectable label that is linked to a second antibody that has binding affinity for said protein or said first antibody.
- 26. The immunodetection kit of claim 23, wherein the immunodetection reagent is a detectable label that is linked to a second antibody that has binding affinity for a human antibody.
- 27. A method of generating an immune response, comprising administering to an animal a pharmaceutically acceptable composition comprising an immunologically effective amount of a protein that has a molecular weight of about 13 kD, as determined by SDS/PAGE, and is isolatable from B. burgdorferi.
- 28. The method of claim 27, wherein the composition further comprises a B. burgdorferi OspA OspB, OspC or OspD protein.
- 29. The method of claim 27, wherein the 13 kD protein is a recombinant protein.
- 30. A mutant B. burgdorferi that lacks the OspA, OspB, OspC and OspD proteins.

